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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,080	07/16/2006	Claudio Giordano	47966.11.1	7534

22859 7590 05/21/2010  
INTELLECTUAL PROPERTY GROUP  
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MINNEAPOLIS, MN 55402

EXAMINER
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DAVIS, ZINNA NORTINGTON

ART UNIT	PAPER NUMBER
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1625

MAIL DATE	DELIVERY MODE
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05/21/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,080	<b>Applicant(s)</b> GIORDANO ET AL.	
	<b>Examiner</b> Zinna Northington Davis	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7-10, 14-18 and 22-24 is/are rejected.
- 7) ☒ Claim(s) 2-6, 11-13, and 19-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

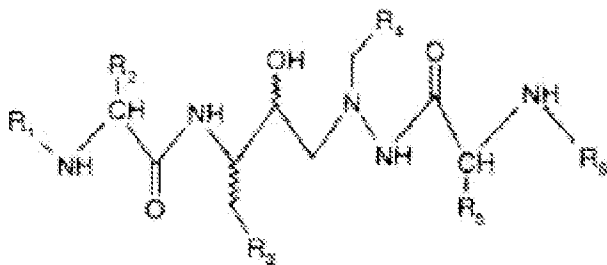
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. Claims 1-24 are pending in the application.
2. Based upon the response filed February 18, 2010, the rejections based upon 35 U.S.C. 112, 2<sup>nd</sup> paragraph and 35 U.S.C. 103(a) based upon Giordano et al. in view of Stanforth et al. are withdrawn.
3. The amendment filed February 18, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: of formula 1,



wherein in formula 1

R<sub>1</sub> is a lower alkoxy carbonyl,

R<sub>2</sub> is a secondary or tertiary lower alkyl or lower alkylthio-lower alkyl,

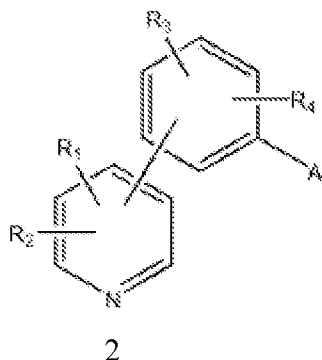
R<sub>3</sub> is phenyl that is unsubstituted or substituted by one or more lower alkoxy radicals, or C4-C8 cycloalkyl,

R<sub>4</sub> is a phenyl or cyclohexyl each substituted in the 4-position by unsaturated heterocyclyl that is bonded by way of a ring carbon atom, has from 5 to 8 ring atoms, contains from 1 to 4 heteroatoms selected from nitrogen, oxygen, sulfur, sulfinyl and sulfonyl and is unsubstituted or substituted by lower alkyl or phenyl-lower alkyl,

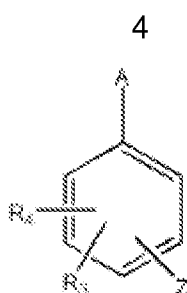
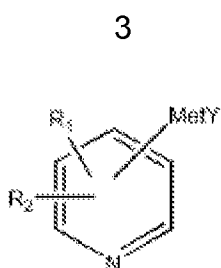
R<sub>5</sub>, independently of R<sub>2</sub>, has one of the meanings mentioned for R<sub>2</sub>, and

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$R_6$ , independently of  $R_1$ , is lower alkoxy carbonyl, comprising preparing an intermediary of formula 2



by a dropwise addition of a solution containing a compound of formula 3 to a solution containing a compound of formula 4



in which in formulas 2, 3, and 4:

Met represents Mg or Zn;

Y represents Cl, Br, I or acetoxy;

Z represents I, Br, Cl, triflate, sulphonate, phosphate;

$R_1$ ,  $R_2$ ,  $R_3$ ,  $R_4$ , which are the same as one another or different, represent hydrogen, a linear and/or branched  $C_1$ - $C_4$  alkyl, and/or an aryl, and/or a heteroaryl, or  $R_1$  and  $R_2$  and/or  $R_1$  and  $R_4$ , taken together form a  $C_3$ - $C_8$  ring, an aryl and/or a heteroaryl;

A represents  $-COR_5$ , where  $R_5$  represents hydrogen, a linear and/or branched  $C_1$ - $C_4$  alkyl, and/or an aryl, and/or heteroaryl, or

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A represents  $-\text{COR}_5\text{O}(\text{R}_6)(\text{OR}_7)$  where  $\text{R}_5$  has the meaning described above and  $\text{R}_6$  and  $\text{R}_7$ , which are the same as one another or different, represent a linear and/or branched  $\text{C}_1\text{-C}_4$  alkyl, and/or an aryl, and/or heteroaryl, or  $\text{R}_6$  and  $\text{R}_7$  joined together, represent a  $\text{C}_1\text{-C}_8$  alkyl or alkenyl, in the presence of catalytic systems based on palladium or nickel.

4. Applicant is required to cancel the new matter in the reply to this Office Action.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. At page 2 of the specification, the heterocyclic derived described in International patent application WO97/40029, which is incorporated herein by reference, is now the claimed. The specification fails to describe essential matter which is critical or essential to the practice of the invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Essential subject matter is improperly

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incorporated by reference. See 37 CFR 1.57 which is appears below:

- (c) “Essential material” may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. “Essential material” is material that is necessary to:
- (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112;

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 7-10, 14-18, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claims 1 and 23, for the radicals,  $R_6$  and  $R_7$  joined together, is C2-C8 alkenyl intended?

B. At claims 7-10, 14-18, and 22, the recitation of the phrase “preferably” is generic and sub-generic which is improper.

C. At claim 24, what compound is intended by BMS-23262.

9. Claims 2-6, 11-13, and 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

12. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

14. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Zinna Northington Davis/*

**Zinna Northington Davis  
Primary Examiner  
Art Unit 1625**